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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,300	08/27/2003	Paramita Bandyopadhyay	00782.US1	5398

25533 7590 06/07/2005

PHARMACIA & UPJOHN
301 HENRIETTA ST
0228-32-LAW
KALAMAZOO, MI 49007

EXAMINER

PICKETT, JOHN G

ART UNIT	PAPER NUMBER
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3728

DATE MAILED: 06/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

5/8

Office Action Summary

Application No.

10/649,300

Applicant(s)

BANDYOPADHYAY ET AL.

Examiner

Gregory Pickett

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. This Office Action acknowledges the applicant's Amendment submitted 21 March 2005. Claims 1-33 are pending in the application.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Drawings

3. The drawings filed 21 March 2005 are acceptable.

Claim Rejections - 35 USC § 112

4. In light of the applicant's amendment, the rejection of claims 13, 18, 23, and 29 under 35 U.S.C. 112, 2nd paragraph, is hereby withdrawn.

Claim Rejections - 35 USC § 103

5. Claims 1-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al (US 2002/0058049 A1) in view of Fehn (US 6,194,043) and Groeger (WO 01/51222 A1).

Regarding claim 1, Wong et al discloses a medicinal preparation in a plastic container (see for example, the abstract). Wong et al lacks, or does not expressly disclose, a fluorinated barrier layer.

Fehn discloses that it was known in the art at the time the invention was made to place a fluorinated barrier layer in a container to inhibit cross contamination. Groeger discloses that it was known in the art at the time the invention was made to use fluorinated polymer for the storage of medicinal components. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the container of Wong et al from a fluorinated polymer, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

As to claims 2-4, 7 and 8, Wong discloses the claimed medicinal preparation.

As to claims 5 and 6, Fehn discloses the claimed materials in a small volume bottle.

Regarding claims 9-16, the package of Wong-Fehn-Groeger discloses the claimed methods by presentation

While claims 17-33 are directed towards particular methods for increasing stability, preventing loss of an ingredient, or reducing transfer of an impurity, the only method steps presented are the provisions of the structures of claims 1-8. As such, the method of Wong-Fehn-Groeger, as applied to claims 9-16, discloses the claimed invention.

Response to Arguments

6. Applicant's arguments filed 21 March 2005 have been fully considered but they are not persuasive.

7. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Wong clearly discloses the claimed medicinal preparation; Fehn and Groeger disclose the suitability of the claimed material for the prevention of cross contamination, with Fehn disclosing the suitability of a fluorinated barrier layer.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of


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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory Pickett whose telephone number is 571-272-4560. The examiner can normally be reached on Mon-Fri, 11:30 AM - 8:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on 571-272-4562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Greg Pickett
Examiner
31 May 2005



Mickey Yu
Supervisory Patent Examiner
Group 3700